TITLE OF INVENTION

Intravascular Infusion Site Anti-Tamper Guard

Having Means For Site Inspection

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not Applicable

BACKGROUND OF THE INVENTION

1. Field of Invention

[0003] The invention pertains to devices for stabilizing a catheter inserted at intravascular and intravenous infusion sites. More particularly, this invention pertains to a tamper resistant device for covering and securing a catheter inserted at an infusion site while providing rapid visual inspection of the infusion site and adjacent tissue for indications of infiltration and extravasation of medications.

2. Description of the Related Art

[0004] In the field of medical care, an urgent and rapidly growing need exists for protection of readily accessible intravenous infusion sites (i.e. dermal sites for injection of medication into veins), and/or intravascular infusion sites (i.e. dermal sites for injection of medication

into arteries or veins), for young patients suffering from AIDS/HIV, cancer, or similar life-threatening diseases, and patients of about forty-five and older suffering from AIDS/HIV, cancer, or advanced delirium, dementia and/or Alzheimer's disease. These young and elderly patients typically require every readily accessible infusion site to be utilized for long-term infusion of AIDS/HIV treatment medications or cancer treatment medications. The medications utilized for treatment of AIDS/HIV, cancer, delirium, advanced dementia and/or Alzheimer's disease are typically highly caustic to the vascular walls and serve as a vesicant agent when allowed to infiltrate external of veins or arteries and into adjacent dermal and subdermal tissues. In addition, for young patients and elderly patients requiring treatment of chronic diseases, the frequently utilized veins tend to be reused and frequently deteriorate from use, which require medical practitioners to seek access to a multitude of additional infusion sites on each patient. After the preferred intravenous sites are used to the point of deterioration, then access to an infusion site into an artery is selected, with the requirement for hospitalization. Patients that receive continuous or intermittent infusion of caustic and/or vasoconstrictive medications for treatment of the above identified diseases can readily suffer from tissue degeneration and atrophy, ischemic necrosis and sloughing of tissue if the medications

infiltrate from veins or arteries and into dermal tissue proximal of the infusion site(s). Infiltration of medications from a vein or artery due to a dislodged catheter can rapidly initiate: erythema venenation, edema, pain, and necrosis of the dermal and subdermal tissues proximal of the infusion site. Extensive tissue damage due to infiltration of medications into dermal and subdermal tissues is generally referred to as extravasation, and is typically caused by a catheter that is displaced from proper insertion in the target vasculature at the infusion site. For very young patients, the catheter may be displaced by unintended actions of the patient. For older patients that suffer from delirium, dementia, or are chemically sedated, and/or are partially restrained during treatment, there is a significant risk of the catheter being displaced from the infusion site by the unintended or confused actions of the patient. If the patient does not understand the benefits of maintaining a properly positioned catheter at an infusion site, the patient may disrupt the catheter and/or associated tubing at the infusion site. Infiltration of the medication(s) initiate tissue damage leading to extravasation of the patient's dermal and subdermal tissue. Therefore, the medical practitioner must frequently visually inspect the infusion site(s) for each patient under his/her care, with a minimum of disruption of the patient and preferably no movement of the infusion site cover. In

addition, if visual inspection suggests infiltration leading to extravasation proximal of the infusion site, the medical practitioner must be provided rapid access to the catheter inserted at the infusion site. Paradoxically, the catheter and tubing associated with the infusion site must be protected from unintentional or intentional tampering by the patient.

[0005] The preferred infusion site is selected to provide rapid access by medical practitioners to one or more of the patient's veins or certain arteries in emergency situations. The vein or artery selected typically provides rapid access for the medical practitioner for changing of tubes, medication storage bags and for inspecting the infusion site(s). The infusion site is also generally accessible to tampering by the patient. Typical infusion sites are located on the patient on the hand, wrist, forearm, elbow, upper arm, upper chest, groin, foot and ankle (typically utilized for the very young). If the patient is not aware of the benefits of keeping the infusion site intact, or is suffering from delirium, dementia, the patient may attempt to dislodge the catheter without the medical practitioner's knowledge.

[0006] If the infusion site is disrupted and the catheter is partially dislodged or withdrawn from the interior of the vein but remains within the subcutaneous tissue for as little as one to two hours, leakage

identified as extravasation occurs. The medicinal fluids utilized for treatment of HIV/AIDS or cancer typically include vasoconstricting agents and/or caustic agents, with the extravasation of the medicinal fluids rapidly degrading surrounding perivascular tissue, subcutaneous tissue, and dermal tissue over approximately six hours to about twenty-four hours. Extravasation occurs due to the vasoconstrictive or caustic agent properties of a multitude of medications utilized for treatment of patients suffering from delirium, dementia, cancer, and/or AIDS or other chronic diseases. If extravasation of vasoconstrictive or caustic agents is not detected by frequent visual inspections of the infusion site, and treatment is not immediately provided for the dermal tissue undergoing degradation from exposure to the caustic agents (*i.e.* within approximately six hours to about twenty-four hours of initial infiltration), necrosis of the dermal and subdermal tissues can readily occur in twenty-four to forty-eight hours, leading to the onset of gangrene of tissue in about seven to ten days. Patients suffering from delirium, dementia or who are heavily sedated, will not readily identify detrimental changes to dermal tissues proximal of each infusion site. In order to protect the patient, rapid detection is needed by a medical practitioner conducting frequent visual inspections of each infusion site. Rapid and frequent visual inspections are facilitated only if a covering over each

infusion site provides a clear view of each site without requiring physical adjustments for viewing of each site. If extravasation occurs, the infusion site at the location of infiltration is lost, and the potential infusion sites on the extremity proximal of the disrupted infusion site are typically not functional also.

[0007] To guard against extravasation of medication in very young and aged patients receiving medications including vasoconstrictive and/or caustic agents, most hospital protocols require visual inspections of each of one or more infusion site(s) for each patient by a medical practitioner on a recurring hourly basis or a similar schedule. The frequency of visual inspections can be overwhelming for a typical patient to medical staff ratio in many non-critical care facilities of about eight to ten patients to one medical practitioner. Further, the frequency of visual inspections are a real burden to the nursing staff even for a typical patient to medical staff ratio in many intensive care units of about two to three patients to one medical practitioner, if the hospital is adequately staffed.

[0008] It is preferred that a protective guard device is configured to be flexible and sized to encircle a portion of a patient's body for covering an infusion site to limit tampering by the patient. It is also preferred

that a tamper resistant guard is provided with means for rapid visual inspection of the infusion site and the adjacent dermal surfaces without medical personnel having to manipulate the guard to uncover and recover the infusion site after visual inspection.

[0009] Therefore, a need exists for a tamper resistant device that covers and maintains the proper positioning of a catheter and associated tubing at an infusion site, while providing means for rapid visual inspection of the infusion site and surrounding dermal tissue by a medically trained professional.

BRIEF SUMMARY OF THE INVENTION

[0010] According to one embodiment of the present invention, a tamper resistant guard is provided for covering an intravascular infusion site having a catheter inserted through a dermal surface of the patient. The tamper resistant guard provides for rapid visual inspection of the infusion site for indications of infiltration of fluids and disruption or degradation of dermal tissue proximal to the infusion site. The tamper resistant guard includes a base panel of sufficient size and flexibility to cover the infusion side and adjacent dermal tissue. An open portion is disposed in the base panel and is sufficiently sized to be positioned over the infusion site. The base panel further includes a receiving end having first and second means for attaching disposed respectively on an outer

receiving surface and a dermal receiving surface. The open portion provides for visual inspection of the infusion site and adjacent dermal tissue without requiring adjustment of the base panel by a medical practitioner.

[0011] The panel open portion is positioned in covering relationship over the infusion site and is maintained against the patient's dermal surface proximal of the infusion site by means for retaining extended from the panel and configured to be releasably attached to the panel second means for attaching. A resilient flap having a flexible window therein is hingedly secured on the panel outer receiving surface. The flap flexible window is sized for positioning in register with the panel open portion. The flap includes an attaching side having means for fastening thereon for releasably securing the flap attaching side to the panel first means for attaching on the outer receiving surface with the window in register with the panel open portion and positioned in covering relationship over the infusion site. The flap attaching side and means for fastening is releasably secured to the panel first means for attaching in an overlapping relationship with the panel to cover and retain therebetween a selected length of tubing extended from the infusion site. The tamper resistant guard provides a covering relationship over the infusion site and provides an overlapping relationship with the panel and a selected length

of tubing extended from the infusion site to minimize patient disruption of the infusion site and associated tubing. The tamper resistant guard allows rapid visual inspection of the infusion site through the flap flexible window and panel open portion by the medical practitioner to provide early detection for infiltration and extravasation of medicinal fluids and treatment for degeneration of dermal tissue proximal to the infusion site.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0012] The above-mentioned features of the invention will become more clearly understood from the following detailed description of the invention read together with the drawings in which:

Figure 1 is an exploded view of a tamper resistant guard of the current invention, illustrating a flexible base panel having an opening therein and a flexible flap having a resilient window therein;

Figure 2 is a perspective view of the flexible flap attached to the outer receiving surface of the base panel of Figure 1, with the base panel positioned in an overlapping configuration and having a portion of tubing secured between the flap and the base panel;

Figure 3 is an exploded view of an alternative embodiment of Figure 1, illustrating a flexible flap having a flexible window therein and a second

flap positioned to be attached to by surfaces with hook and loop fastening means thereon;

Figure 4 is a perspective view of the flexible flap and second flap attached to the outer receiving surface of the base panel of Figure 3, with the base panel positioned in an overlapping configuration and having a portion of tubing secured between the flap and the base panel;

Figure 5a is a perspective view of a tubing tie having a fastening material thereon for releasably securing the tie to the base panel;

Figure 5b is a perspective view of a tubing tie positioned to encircle a portion of tubing to be secured between the flap and the base panel;

Figure 6 is a cross-section view of the guard base panel in an overlapping configuration, with a portion of tubing positioned between the base panel and the overlying flap;

Figure 7 is a side view of a medial portion of a tamper resistant guard having a resilient flap and window protectively covering a forearm infusion site;

Figure 8 is a side view of a distal portion of the guard of Figure 7, illustrating a flap attaching side covering tubing ties and tubing extended

from the forearm infusion site;

Figure 9 is a side view of a tamper resistant guard having a resilient flap and window protectively covering an antecubital infusion site;

Figure 10 is a side view of a distal portion of the guard of Figure 9 having a flap attaching side covering a tubing ties and tubing extended from the antecubital infusion site;

Figure 11 is a side view of an alternative embodiment of the tamper resistant guard of Figure 9, illustrating a resilient flap and window covering an antecubital infusion site and two retaining straps encircling the elbow;

Figure 12 is a side view of a distal portion of the guard of Figure 11 having a flap window covering a second antecubital infusion site and a flap attaching side covering two tubes extended from two infusion sites;

Figure 13 is a side view of a medial portion of a tamper resistant guard having a resilient flap and window covering an upper arm infusion site;

Figure 14 is a side view of a distal portion of the guard of Figure 13, illustrating a flap attaching side covering tubing connected to the upper

arm infusion site;

Figure 15 is a side view of a tamper resistant guard having a resilient flap and window covering an outer upper arm infusion site;

Figure 16 is a side view of a medial portion of the guard of Figure 15 having a flap attaching side covering tubing extended from the upper arm infusion site and with two retaining straps encircling the elbow;

Figure 17 is a perspective view of a tamper resistant glove guard having a resilient flap and window covering an infusion site on the back side of a hand;

Figure 18 is a perspective view of the palmar portion of the glove guard of Figure 17 illustrating a flap attaching side extendable to cover a plurality of tubing ties and tubing extended from the hand infusion site;

Figure 19 is a perspective view of a tamper resistant glove guard having a resilient flap and window covering a carpal infusion site;

Figure 20 is a perspective view of the palmar portion of the glove guard of Figure 19, illustrating a flap attaching side covering a plurality of tubing ties and tubing extended from the carpal infusion site;

Figure 21 is a perspective view of a tamper resistant guard having a

resilient flap and window covering a subclavian infusion site;

Figure 22 is a perspective view of the back of a patient illustrating the means for retaining for maintaining the guard in covering relationship over the subclavian infusion site;

Figure 23 is a perspective view of a tamper resistant guard having a resilient flap and window covering one jugular infusion site on the neck;

Figure 24 is a perspective view of a tamper resistant guard having a resilient flap and window covering a second jugular infusion site on the neck;

Figure 25 is a perspective view of a tamper resistant guard having a resilient flap and window covering a femoral infusion site proximal of a patient's groin;

Figure 26 is a perspective view of the means for retaining for maintaining the guard in covering relationship over the femoral infusion site;

Figure 27 is a side view of a tamper resistant guard having a resilient flap and window covering a child's ankle infusion site;

Figure 28 is a side view of a tamper resistant guard having a

resilient flap and window covering an adult's ankle infusion site; and

Figure 29 is front perspective view of a tamper resistant guard having a resilient flap and window covering an adult's foot infusion site.

DETAILED DESCRIPTION OF THE INVENTION

[0013] A tamper resistant guard is illustrated at **10** in Figures 1 and 2 for covering a portion of the dermal tissue **12** proximal of a patient's forearm infusion site **46** having a flexible catheter **14** inserted therein. The guard device **10** includes a base panel **20** of sufficient size and flexibility to cover an infusion site **46** and dermal tissue **12** proximal of the infusion site. The base panel **20** further includes a receiving end **24**, a first retaining end **26**, and an open portion **30** therebetween. A resilient flap **34** is hingedly secured at a junction **36** formed by attaching a flap first side **36'** along a medial portion **22** of the base panel **20**. The resilient flap **34** includes a flexible window **40** therein that is aligned in register with the panel open portion **30**, in order to provide means for rapid visual inspection by a medical practitioner of the covered dermal tissue **12** for indications of infusion site tampering, and/or for indications of infiltration and extravasation of medicinal fluids intended to be

transmitted intravenously (vein) or intravascularly (artery or vein), and for indications of symptoms of tissue swelling and degradation and tissue necrosis proximal of the infusion site.

[0014] A plurality of embodiments are disclosed herein for configurations and uses of the guard device **10** in order to provide an optimal configuration for a protective cover over each one of a plurality of infusion sites that can be selected by the medical practitioner. Typically at each infusion site, a flexible catheter **14** is inserted through the dermal tissue **12**, through the subcutaneous tissue, and into a vein or an artery for intravascular delivery of medications. Depending on the number of infusion sites that are utilized, or have been previously utilized for a patient, a candidate infusion site is selected from a plurality of infusion sites located on the patient's hand, wrist, forearm, elbow, upper arm, neck, upper chest, groin, ankle and/or foot as described herein. A portion of fluid transfer tubing **16** is connected to the inserted catheter **14** for extension under the guard device **10** along a significant distance from the patient to a medication dispensing bag (not shown) that is typically positioned next to the patient or is positioned in an elevated position above the patient.

[0015] One embodiment of the guard device **10** is illustrated in

Figures 1 - 4 and includes an elongated base panel **20** that is positioned to encircle either of the patient's forearms in order to cover a forearm infusion site **46**. The base panel **20** is preferably flexible and composed of a stretchable, non-allergenic material having a surface texture that is non-irritating to a patient during extended contact with the patient's skin. The base panel **20** is sufficiently sized to be positioned to encircle the patient's forearm (see Figs. 7 - 8), or to cover the patient's elbow and forearm (see Figs. 9 - 12), or to cover the patient's upper arm and elbow (see Figs. 13 - 16).

[0016] One embodiment of the base panel **20** includes a flexible length of material selected from a range of five inches for a child forearm embodiment, to about twenty inches for an adult, with a preferred length of about twelve inches for an adult forearm embodiment. A width for the base panel **20** is selected from a range of about three inches for a child forearm embodiment, to about nine inches for an adult, with a preferred width of about seven inches for an adult forearm embodiment. When the base panel **20** is positioned to encircle the patient's forearm, as illustrated in Figures 7 and 8, a dermal surface **20'** contacts the patient's skin. A panel outer receiving surface **20"** includes a medial portion **22** on which a medial seam **36** is formed by hingedly securing a flap first side **36'** on the panel outer receiving surface **20"**. Seam **36** is reinforced by stitching

and/or by positioning a strip of hook and/or loop fastening material along the width of surface **20**". The base panel **20** includes a receiving end **24**, having second means for attaching **24'** disposed on an inwardly oriented, dermal receiving surface **28'**. The receiving end **24** further includes an outer faced, first means for attaching **24"** disposed on an outer receiving surface. The receiving end **24** and first means for attaching **24"** are positioned in one embodiment proximal of an outer, distal side of the patient's forearm, with the panel open portion **30** and flap window **40** positioned over the forearm infusion site **46** (see Figs. 7 and 8). The second means for attaching **24'** includes at least one strip of fastening material having a plurality of loops thereon, in order to releasably fasten with a plurality of hooks **28'** on the panel retaining edge **26**. The first means for attaching **24"** includes strips of fastening material having a plurality of hooks for releasably engaging with the flap **34** means for fastening **38**. Those skilled in the art will realize that the positioning of the hooks and loops on respective engaging surfaces can be switched.

[0017] In one embodiment, the base panel **20** serves as a protective cover over the infusion site **46** located on a patient's forearm, with the base panel **20** being extended around the patient's extremity and having a panel retainer edge **26** that is releasably secured by means for retaining against the inner faced surface of the panel receiving end **24**. The

retainer edge **26** is securely attached under and against receiving end **24** due to means for retaining **28** bonded to the outer faced surface of the panel first end, also referenced as a retainer end **26** (see Figs. 1 and 2). An alternative configuration including a plurality of panel retainer edges **26'** is illustrated in Figure 3. The means for retaining **28** is preferably composed of a plurality of hooks **28'** that are releasably attachable to material having a plurality of loops **24'** bonded under the panel receiving end **24**. After the medical practitioner has positioned the inserted catheter **14** in the forearm infusion site **46**, the base panel **20** is positioned to encircle the forearm and cover the forearm infusion site **46** by releasably fastening the retainer edge **26** to the retainer end **24** at a junction formed against the dermal receiving surface **24'**. The junction is positioned preferably on the distal side of the forearm to minimize tampering by the patient (see Fig. 8). Those skilled in the art will recognize that the positioning of the hook and loop fastening materials may be reversed from the disclosed configuration, to provide releasable securement of the dermal receiving surface **24'** with the means for retaining **28** on the retainer edge **26**. Regardless of the orientation of the hook and/or loop fastening materials forming the panel means for attaching and panel means for retaining, the panel receiving end **24** and retaining end **26** are releasably attached to each other in an overlapping

configuration or an underlying configuration, thereby positioning the base panel **20** in a covering relationship over the forearm infusion site **46**.

[0018] The guard device **10** further minimizes patient tampering with the forearm infusion site **46** and with tubing **16** extended from the forearm infusion site **46**, by the inclusion of the resilient flap **34** that is hingedly attached along the flap first side **36'** proximal of the outer receiving surface **20"** of the base panel **20**. The flap **34** provides a unique combination of a plurality of protective features including a centrally oriented flexible and resilient window **40** positioned to cover in register alignment with the open portion **30** of the base panel **20**, thereby providing rapid visual inspection of the infusion site while providing at least one layer of protection from intrusion by the patient. The flap **34** includes means for fastening **38** disposed on an inwardly faced surface of a second, distal edge **38'**, for covering engagement and releasably securing a selected length of tubing **16** underneath the flap **34**.

[0019] The flap means for fastening **38** and second edge **38'** are adequately sized to extend past the panel receiving end **24**, and to engage in overlapping relationship with both the first means for attaching **24"** and the adjacently positioned hooks and/or loops **28'** of the means for retaining **28** on the panel retainer edge **26**. Therefore, the plurality of flap

and panel surfaces having hook and loop fastening materials thereon provide a tamper resistant covering orientation **48** forming a gap **44** in which tubing **16** is secured (see Figs. 6 and 8), between the inwardly faced surface of the flap **34**, or a flap extension **34'**, and the outer faced first means for attaching **24"** proximal of the receiving end **24** of the base panel **20**. An additional protective feature of the guard device **10** includes a second means for attaching **24'** that is releasably secured either directly with hooks and/or loops **28'** of the means for retaining **28**, or indirectly by flap extensions **26'** from the means for retaining **28**. The guard device **10**, when positioned on an extremity, requires a patient to manipulate with one hand the flap means for fastening **38** in one direction to separate the flap from engagement with the panel upper surface first means for attaching **24"**, such as in a clockwise direction relative to the extremity or torso. While holding the flap second edge **38'**, or flap extension edge **38"**, in a disengaged position above the first means for attaching **24"**, the patient must manipulate the means for retaining **28** with one hand in an opposing direction relative to the extremity or torso, to separate the means for retaining **28** from the panel second means for attaching **24'** to achieve removal of the flap **34** and base panel **20** from engagement over a typical infusion site **46**.

[0020] The selected length of tubing **16** is further secured in a

generally fixed and distal covering orientation **48** (see Figs. 6 and 8) between the first flap **34** (see Fig. 2), or the flap extension **34'** (see Fig. 4), by a plurality of easily adjustable ties **18** that are releasably secured within a gap **44** between the underside of the first flap **34** or the flap extension **34'** and the receiving surface **20"** of the base panel **20** (see Figs 7 - 10). The adjustable ties **18** include a hook or a loop fastening material on an outer surface **18'**, and on inner surface **18"** having a hook or loop fastening material opposite of the outer surface **18'** to allow each adjustable tie **18** to be separately manipulated to encircle portions of the tubing **16** and to attach to a hook and/or loop surface material on the guard device **10**. Each adjustable tie **18** is positioned by the medical practitioner to attach between the outer faced means for attaching **24"** of the base panel **20**, and the means for fastening **38** on the first flap **34** or the flap extension **34'**. The flap covered adjustable ties **18** thereby provide the medical practitioner with the ability to quickly detach and reattach the tubing **16** within a gap or channel **44** formed between the outer faced means for attaching **24"** proximal of the base panel receiving end **24** and the means for fastening **38** of the flap **34** (see Figs. 2, 4, and 6).

[0021] A guard device **50** for covering an antecubital infusion site **52** is illustrated in Figures 9 and 10. The guard device **50** includes a base

panel **54** that is positioned to encircle either elbow. The base panel **54** includes medial seam **56** that is hingedly attached by stitching, or by utilization of a strip of hook and/or loop fastening material along the width of the panel outer surface **20"**, thereby forming a pivotable junction along the seam **56** to allow a medical practitioner to manipulate a resilient flap **60** into a covering relationship on the panel outer receiving surface **20"**. A panel first edge **58** is extended in an opposing direction from the junction of seam **56** and the flap **60**, in order to encircle the patient's elbow with the base panel **54**. A panel first edge **58** includes second means for attaching **58"** on a dermal receiving surface, with the second means for attaching **58"** composed of hook and/or loop material. The panel second means for attaching **58"** is releasably attachable under a panel first edge **58** having first means for attaching **58'** thereon such as hook and/or loop material, in order to securely fasten the panel **54** in an encircling position over the infusion site **52** on the patient's elbow. A panel open portion **54'** is centrally positioned in the base panel **54** and is a sufficiently sized and shaped opening to provide a view of the elbow infusion site **52** when the base panel **54** is in covering engagement. The resilient flap **60** is releasably positioned to cover the panel open portion **54'** and a portion of tubing **70** extended from the infusion site **52**. The flap **60** includes a resilient window **62** that is preferably sized and shaped

to be aligned in register with the open portion **54'**. The open portion **54'** and flexible window **60** are positioned in register to cover the elbow infusion site **52** and a selected portion of the fluid transfer tubing **70** connected to the inserted catheter **14**. The flap **60** also includes an attaching side **64** having means for fastening thereon **68**, such as hook or loop fasteners, that are releasably secured to the panel first means for attaching **58'** in an encircling configuration over the elbow infusion site **52**. The guard device **50** provides a tamper resistant device that covers the elbow infusion site **52** and associated tubing **70**, **88** while allowing rapid visual inspection of the infusion site **52** through window **62** and panel open portion **54'** for indications of extravasation of medicine and degeneration leading to atrophy of dermal tissues proximal of the antecubital infusion site **52**.

[0022] An alternative embodiment of the guard base panel **54** is illustrated in Figures 11 and 12 and includes a base panel **74** having a medial seam **74'**, an open portion **74"** that is positioned to cover a first antecubital infusion site **52** and a second infusion site **72** proximal of the first antecubital infusion site **52**. The base panel **74** further includes a elbow opening **74'"**, a first means for retaining **76** and a second means for retaining **78** that are each elongated and flexible. Each means for retaining **76**, **78** is extendable from the medial seam **74'** of the base panel

74 to attach at respective distal retaining ends **76'**, **78'** to means for attaching **74"** such as hook or loop fasteners attached on a distal side of the base panel **74**.

[0023] As illustrated in Figure 11, a resilient flap **80** is hingedly attached by stitching along the medial seam **74'**, or by means for fastening such as hook or loop fasteners, to the base panel **74**. The flap **80** includes a flexible transparent window **82** therein, and a distal edge **84** having a means for fastening **84'** that is releasably secured to means for attaching **76"**, **78"** on the respective panel retaining ends **76'**, **78'**, thereby maintaining the window **82** in a covering relationship over both infusion sites **52**, **72**. Flap distal edge **84** provides cover for a portion of tubing **70** and/or a portion of a second tube **88'** extended from the second infusion site **72**. The flap distal edge **84** includes means for fastening **84'** thereon, such as hook or loop fasteners, allowing the flap distal edge **84** to be releasably secured over the respective means for attaching **76"**, **78"** on the distal retaining ends **76'**, **78'**. The base panel open portion **74"** and the flexible window **82** are positioned in register to cover the antecubital infusion sites **52**, **72**. Further, the flap distal edge **84** is releasably secured to cover a selected portion of one or both fluid transfer tubing **70**, **88'** connected to the respective infusion sites **52**, **72**. Therefore, the antecubital guard device **50**, including either base panel

54, **74**, provides a tamper resistant device that covers an infusion site and associated tubing while allowing rapid visual inspection of the infusion site **52** for indications of extravasation of medications and degeneration and atrophy of dermal tissues proximal of infusion site **52**.

[0024] A guard device **100** is illustrated in Figures 13 and 14 for covering an inner, medial upper arm infusion site **102**. The guard device **100** includes a base panel **104** that is positioned to encircle the upper arm and the elbow area of the patient. The base panel **104** is applied around the patient's arm by extending an outer receiving surface having a retaining end **106** and means for retaining **106'** thereon, such as hook or loop fasteners, allowing the receiving end **106** to be releasably secured under a panel receiving end **108** having second means for attaching on a distal side, in order to securely position the base panel **104** to encircle the infusion site **102**. A panel open portion **104"** is positioned in the base panel **104** and is sufficiently sized and shaped to provide a view of the upper arm infusion site **102** when the base panel **104** encircles the upper arm. A resilient flap **110** is attached to the base panel **104** along junction **104'**, by either stitching or a length of hook and/or loop fastening material. The resilient flap **110** is extended to cover the flap open portion **104"**. The flap **110** includes a flexible window **112** sized and shaped to be aligned in register with the panel open portion **104"**, thereby

positioning the flexible window **112** in covering relationship over the infusion site **102**. The flap **110** includes an attaching side **114** having means for fastening **114'** thereon, such as hook or loop fasteners, that are releasably secured to a panel first means for attaching **108'**, such as hook or loop fasteners. Flap attaching side **114** is releasably secured in an overlapping relationship with the panel first means for attaching **108'** with a selected length of tubing **120** therebetween, thereby minimizing patient tampering with the selected length of tubing **120** extended from the upper arm infusion site **102**.

[0025] An alternative guard device **130** configured for application on a patient's upper arm and having an elbow opening is illustrated in Figures 15 and 16. A base panel **134** is positioned in covering engagement over an upper arm infusion site **132**. The base panel **134** includes an upper portion **136** having a distal, receiving end **136'** with upper first means for attaching **136"** thereon, such as hook or loop fasteners. The base panel **134** further includes a lower portion **138** having a distal, receiving end **138'** with lower first means for attaching **138"** thereon. The base panel additionally includes an upper and lower side portions **134'"** having means for retaining **134""** thereon, for extension to encircle the upper arm and forearm in a direction opposite of the panel upper portion **136**, and panel lower portion **138**. The encircling

portions of the base panel upper and lower side portions **134'"** are releasably joined respectively with upper and lower portions **136**, **138**, on the medial side of the upper arm as illustrated in Figure 16. The receiving ends **136'**, **138'** have a second means for attaching **138""** such as hook or loop fasteners (not shown) on a dermal receiving surface of each end **136'**, **138'** to releasably attach the respective hook and/or loop fasteners in an overlapping relationship against the medial side of the arm. Two resilient flaps **140**, **144** are utilized to encircle the upper arm and the forearm proximal of the patient's elbow. A base end of each flap **140**, **144** is hingedly attached at respective junctions **134'** and **134"** by stitching or by means for fastening such as hook or loop fasteners, to respective upper and lower areas of the base panel **134**. As illustrated in Figure 15, the first flap **140** includes at least one flexible transparent window **112** therein, with the window **112** utilized to cover a panel open portion **104"** positioned over the infusion site **132**. A first flap attaching side **140'** is releasably secured by a means for fastening **140"** to a panel first means for attaching **136"**. A second flap **144** includes a second attaching edge **144'** that is releasably secured by a means for fastening **144"** to a forearm portion having the first means for attaching **138"** thereon. The second attaching edge **144'** is utilized to cover a portion of tubing **120** extended from the infusion site **132**. Although not illustrated,

the second flap **144** can include a second window therein for protectively covering a second infusion site positioned similar to infusion sites of Figures 9 - 12. Each respective flap distal edge **140'**, **144'** includes means for fastening **140"**, **144"** thereon, such as hook or loop fasteners, which are releasably secured over the respective means for attaching **136"**, **138"** on the panel outer surfaces. The panel open portion **104"** and the flexible window **112** are positioned in register to cover either of the upper arm infusion sites **102**, **132**. The upper flap **140** and lower flap **144** are releasably secured to cover respective portions of the tubing **120** connected to the either infusion site **102**, **132**. Therefore, either of the guard devices **100**, **130** provide a tamper resistant device that covers an upper arm infusion site and associated tubing. Further, the guard devices **100**, **130** allow rapid visual inspection of either upper arm infusion site **102**, **132** for indications of extravasation of medications and degeneration and atrophy of dermal tissues proximal of an upper arm infusion site.

[0026] A glove embodiment **150** is illustrated in Figures 17 and 18 and includes a glove shaped base panel **154** that is worn to cover a hand infusion site **152**. In order to protectively cover the infusion site **152** on the dorsal side of the hand, a resilient flap **160** is utilized in a covering relationship to cover the infusion site **152**. The flap **160** is extended from

a base junction and seam **160'** that is hingedly attached by stitching proximal of a dorsal portion of the base panel **154**. As illustrated in Figure 17, the dorsal portion of the glove includes at least two finger holes **154"'**, **154""** serving as a binding for maintaining the glove shaped base panel **154** and panel open portion **154'** over the infusion site **152**. The base panel **154** includes a first portion having a thumb opening therein, and includes a second portion identified as a base panel palmar portion **154"**. Base panel **154** and palmar portion **154"** extend to encircle the patient's hand by releasably connecting proximal of the palm area. The base panel **154** includes a dermal receiving surface having a means for retaining such as hook or loop fasteners thereon, that are releasably engaged with a second means for attaching **156** positioned on a palm edge of the panel palmar portion **154"**. The flap **160** includes a flexible transparent window **162** releasably secured in a covering relationship with a dorsal portion of the base panel **154** for maintaining an overlapping relationship of the window **162** in register with the panel open portion **154'** positioned over the infusion site **152**. The flap **160** includes an attaching side **164** having means for fastening **164'** thereon, such as hook or loop fasteners, that are releasably secured to the palm first means for attaching **158** to cover the panel palmar portion **154"**. A selected length of tubing **168** is releasably secured by a plurality of

adjustable ties **18** between the flap **160** and the panel palmar portion **154"**, thereby protectively covering the tubing **168** from tampering by the patient.

[0027] An alternative glove embodiment **170** is provided for covering a carpal and/or wrist vein or artery infusion site **172** is illustrated in Figures 19 and 20. A glove shaped base panel **174** includes a thumb opening and an elongated opening through which the patient's fingers extend. The base panel **174** includes an open portion **174'** within the portion of the panel covering the carpal area of the hand. The panel **174** further includes a first outer receiving surface **178** having first means for attaching **178'** thereon. A panel dermal receiving surface **176** includes a second means for attaching **176'** thereon, such as hook or loop fasteners, that are releasably engaged with an underside surface of the first means for attaching **176'** positioned along a palmar area of the patients hand.

[0028] A resilient flap **180** is extended in an overlapping relationship with the panel open portion **174'** in order to maintain a flap window **162** covering the carpal infusion site **172**. The flap **180** includes an attaching side **182** having means for fastening **182'** thereon, such as hook or loop fasteners, that are releasably secured to the palm first means for attaching **178'** to cover the patient's palm. A selected length of tubing

168 is releasably secured by a plurality of adjustable ties **18** between the flap **180** and the panel receiving end **178**, thereby protectively covering the tubing **168** from tampering by the patient. In order to protectively cover the infusion site **172** on the carpal portion of the hand, a resilient flap **180** is positioned in an overlapping relationship over the panel open portion **174'** disposed to cover the infusion site **172**. The resilient flap **180** includes a flexible window **184** therein, and includes a flap base end **180'** that is hingedly attached along junction **180"** on the panel outer surface by stitching to secure the flap base end **180'** proximal of the palm portion of the glove **170**. As illustrated in Figure 20, the flap **180** includes an attaching side **182** having means for fastening **182'** thereon, which is releasably secured to first means for attaching **178'** on outer receiving surface **178** of the glove. A selected length of tubing **168** is releasably secured by a plurality of adjustable ties **18** between the flap attaching side **182** and first means for attaching **178'**, thereby providing a covering relationship over the tubing **168** to protect from tampering by the patient. Either of the glove guard embodiments **150**, **170** provides a tamper resistant device that covers an hand or carpal infusion site and associated tubing while allowing rapid visual inspection of either infusion site **152**, **172** for indications of extravasation of medications and degeneration and atrophy of dermal tissues proximal of the infusion sites

152, 172.

[0029] A subclavian embodiment **200** includes positioning a guard device upon the dermal surface of a patient's upper right or upper left portion of his/her chest for covering a subclavian vein or artery infusion site **202** as illustrated in Figures 21 and 22. A subclavian base panel **204** is provided having a generally rectangular or pentagonal base of resilient material having an open portion **204'** therein. An upper side **206** of an outer faced panel surface includes means for attaching thereon, such as hook or loop fasteners, and a lower side **208** of the outer faced panel surface includes means for attaching disposed thereon. The base panel **204** includes means for retaining such as at least one torso strap **220** having at least one connecting end **222** with hook or loop fasteners thereon. The torso strap **220** is retained around the patient by extending the strap **220** between the panel lower means for attaching **208** and corner **208'**.

[0030] As illustrated in Figure 21, a resilient flap **210** is releasably attached to an outer receiving surface of the panel **204**. The resilient flap **210** includes a flexible window **212** therein, with the flap window **212** being positioned in register over the panel open portion **204'** when the panel **204** is positioned over the subclavian infusion site **202**. A flap

medial portion **214** is hingedly attached by stitching **214'** proximal to the panel lower portions **208, 208'**. A flap upper portion **216**, also identified as a first attaching side, includes means for fastening **216'** thereon, such as hook or loop fasteners, which is releasably fastened proximal to the panel upper side means for attaching **206**. The lower flap perimeter includes means for fastening **216"** thereon, such as hook or loop fasteners, that are releasably secured to the panel lower portion means for attaching **206'**. Therefore, the subclavian embodiment **200** provides a tamper resistant guard device that covers an infusion site and associated tubing while allowing rapid visual inspection of the infusion site **202** for indications of extravasation of medications and degeneration and atrophy of dermal tissue proximal of the patient's subclavian infusion site **202**.

[0031] A neck embodiment **230** includes positioning the tamper resistant guard on the patient's neck for covering either of two external jugular vein infusion sites **232, 232'**, as illustrated in Figures 23 and 24. A base panel **234** includes an elongated length of flexible material having a first end **238** having means for retaining **238'** thereon, such as hook or loop fasteners. A panel receiving end **236** having a first means for attaching **236"** thereon, is extended from a medial portion of the base panel **234** in an opposing direction from the first end **238** in order to encircle the patient's neck. The means for retaining **238'** is attached

under the receiving end **236** to a second means for attaching **236'** (not shown), in order to maintain the receiving end **236** proximal of the back of the neck to minimize tampering by the patient. The base panel **234** can be readily repositioned in a mirror-image position on the left neck area of the patient as illustrated in Figure 24. A panel open portion **234"** is positioned over the right external jugular vein infusion site **232** when the base panel **234** is properly positioned to encircle the patient's neck. A panel means for attaching **236'**, such as hook or loop fasteners, is oriented along the base panel **234** proximal to the patient's neck.

[0032] Included in the neck embodiment **230** is a resilient flap **240** having means for fastening **246** thereon is releasably secured to the panel means for attaching **236'**, in order to securely cover a selected portion of tubing **248, 248'** extended from either of the infusion site **232, 232'**. A flap flexible window **242** is positioned in register with the panel opening **234"** when the flap window **242** is securely covering the infusion site **232**. The flap **240** is hingedly secured by stitching **244'** at a junction of the flap base edge **244** and the outer receiving surface of the panel **234** by stitching **244'**. The flap attaching side **246** having means for fastening **246'** thereon is releasably secured in overlapping relationship on the panel first means for attaching **236**. The hinged movement of the resilient flap **240** allows a medical practitioner to lift the flap attaching

side **246** without removing the base panel **234** from the patient's neck, thereby allowing a detailed inspection of the dermal tissue proximal of the infusion site and catheter, and allowing disconnecting and reconnecting of tubing **248** extended from the catheter. The means for retaining **238** includes a first panel end of flexible panel material extending from the junction of the panel with flap base edge **244**. The means for retaining **238** is positioned to extend around the front of the patient's neck for connection to the panel second means for attaching **236'** (not shown), in order to releasably secure the base panel to the patient's neck. A front neck padding unit **238"** if utilized to maintain the patient's neck and chin in an extended position apart from either of the two jugular infusion sites **232**, **232'**. Therefore, the neck embodiment **230** provides a tamper resistant device that covers either of the jugular infusion sites **232**, **232'** and associated tubing **248**, **248'** while allowing rapid visual inspection of either jugular infusion site for indications of extravasation of medications and degeneration and atrophy of dermal tissues proximal of either jugular infusion site **232**, **232'**.

[0033] A groin embodiment **250** includes positioning the modified guard device for covering either of a left femoral infusion site **252** as illustrated in Figures 25 and 26, or a right femoral infusion site **252'** (not illustrated). A left base panel **254** and a right base panel **254'** are mirror

designs, therefore the following discussion is directed to a left side view as illustrated in Figures 25 and 26. The base panel **254** includes a panel opening **254'** that is positioned over the femoral artery infusion site **252**, and includes a first side panel **256** that partially encircles the patient's thigh. On an inner or outer surface of the first side panel **256**, a first means for retaining **256'**, such as hook or loop fasteners, is disposed for attachment of each end of a plurality of straps **258'**, **258"** that extend around the back of the patient's thigh to attach to a second side panel **258** having additional hook or loop fasteners **256'** on an inner or outer surface (see Fig. 26).

[0034] The groin embodiment **250** further includes a resilient flap **260** having an attaching side **266** with means for fastening **268** thereon. The flap attaching side **266** is extended to be releasably secured to the second side panel **258** having first means for attaching **258'** thereon in order for the flap attaching side **266** to cover in overlapping relationship a selected portion of tubing **270** extended from the femoral infusion site **252**. A flap flexible window **262** is positioned in register with the panel opening **254"** over the femoral infusion site **252** when the flap attaching side **266** is releasably secured to the first means for attaching **258'**. The flap **260** is hingedly secured at a base edge **264** by stitching **264'**. The flap means for fastening **268** is oriented along the flap attaching side **266**

and is releasable from the panel first means for attaching **258'** to allow a medical practitioner to conduct a detailed inspect of the selected length of tubing **270** and/or the dermal surfaces proximal of the femoral infusion site **252**. The groin guard **250** provides a tamper resistant device that covers a femoral infusion site and associated tubing while allowing rapid visual inspection of the femoral infusion site **252** (right femoral site not shown) for indications of extravasation of medications and degeneration and atrophy of dermal tissues proximal of the femoral infusion site **252**.

[0035] A child's ankle guard embodiment **300** includes positioning a small, child-sized ankle guard for covering a child's ankle infusion site **302** as illustrated in Figure 27. A base panel **304** includes a panel opening **304'** that is positioned over the child's ankle infusion site **302**, and includes a pliable outer receiving end **306** that extends from junction encircles the patient's ankle. A lower portion **304"** of the base panel **304** is utilized to maintain the panel opening **304'** over the child's ankle infusion site **302**. The panel receiving end **306** includes a first means for attaching **308**, such as hook or loop fasteners positioned on a panel outer receiving surface that are releasably attachable to a means for fastening **318** disposed on an attaching side **316** of a resilient flap **310**. A panel first end **304"'** is extendable around the side of the child's ankle opposite the infusion site **302** for connection by a means for retaining (not shown),

such as hook or loop fasteners, under the panel receiving end **306**.

[0036] The flap attaching side **316** with means for fastening **318** thereon is releasably secured to the panel first means for attaching **308** in order for the flap attaching side **316** to securely cover a selected portion of tubing **320** extended from the child's ankle infusion site **302**. A flap flexible window **312** is positioned over and in register with the panel opening **304'** when the flap window **312** is securely covering the ankle infusion site **302**. The flap **310** is hingedly secured at a base edge **314** by stitching **314'**. The flap means for fastening **318** is oriented along the flap attaching side **316** and is releasable from the panel first means for attaching **308** in order to allow a medical practitioner to conduct a detailed inspection of the infusion site **302** and the associated length of tubing **320** sandwiched under the flap attaching side **316**. Therefore, the ankle guard **300** provides a tamper resistant device that covers an infusion site and associated tubing while allowing rapid visual inspection of either a right or left ankle infusion site **302** for indications of extravasation of medications and degeneration and atrophy of dermal tissues proximal of the child's ankle infusion site **302**.

[0037] An adult's ankle guard embodiment **350** includes positioning a large sized guard for covering an adult's ankle infusion site **352** as

illustrated in Figure 28. A resilient panel **354** includes a panel opening **354'** that is positioned over the adult's ankle infusion site **352**. The panel includes an first end **356'** that is extended against a front portion of the patient's ankle and a lower portion **354"** that is utilized to maintain the panel opening **354'** over the adult's ankle infusion site **352**. A panel receiving end **358** extends around the adult's ankle and includes first means for attaching **258'** such as hook or loop fasteners, that are disposed on an outer receiving surface of the panel receiving end **358**. The panel receiving end **358** further includes a second means for attaching **358"** (not shown) disposed on the panel dermal receiving surface for releasably attaching to the panel first end **356'** extended around the front portion of the adult's ankle.

[0038] A resilient flap **360** having an attaching side **366** with means for fastening **368** thereon is releasably secured to the panel means for attaching **356'**, in order for the flap attaching side **366** to securely cover a selected portion of tubing **370** extended from the adult's ankle infusion site **352**. A flap flexible window **362** is positioned in register with the panel opening **354'** when the flap window **362** is releasably secured to cover the ankle infusion site **352**. The flap **360** is hingedly secured to the base panel **354** at a junction formed by a flap base edge **364** stitched **364'** to the base panel **354**. The flap means for fastening **368** is oriented

along the flap attaching side **366** and is releasable from the first means for attaching **358** on outer faced panel surface, in order to allow a medical practitioner to conduct a detailed inspection of the infusion site **352** and the selected length of tubing **370** covered by the flap attaching side **366**. Therefore, the ankle guard **350** provides a tamper resistant device that covers an ankle infusion site and associated tubing **370** while allowing rapid visual inspection of either left or right ankle infusion site **352** for indications of extravasation of medications and degeneration and atrophy of dermal tissues proximal of the ankle infusion site **352**.

[0039] An adult's foot embodiment **380** is provided for covering an adult's foot infusion site **382** as illustrated in Figure 29. A lower base panel **384** is disposed to encircle the patient's foot, and includes an upper panel **384'** that encircles the patients ankle. The lower base panel **384** includes a lower panel first end having means for retaining **384"** thereon, such as hook or loop fasteners, that is positioned to be releasably fastened under a panel receiving end **386**. A connecting portion of flexible material extends between the upper panel **384'** and a lower panel **384** having a panel opening **384"'** therein, which is positioned over the adult's foot infusion site **382**. The panel receiving end **386** includes a receiving edge **388** having first means for attaching **388'** thereon, such as hook or loop fastening material, that is disposed on the upper side of the

lower base panel **384** proximal of the distal side of the patient's foot.

[0040] A resilient flap **390** having an attaching side **396** with means for fastening **398** thereon is releasably secured to the panel first means for attaching **388'**, in order for the flap attaching side **396** to securely cover in overlapping relationship a selected portion of tubing **400** extended from the adult's foot infusion site **382**. A flap flexible window **392** is positioned in register with the panel opening **384"'** when the flap window **392** securely covers the foot infusion site **382**. The flap **390** is hingedly secured at a base edge **394** by stitching **394'** to the lower base panel **384**. The flap means for fastening **398** is oriented along the flap attaching side **396** and is releasable from the first means for attaching **388'**, in order to allow a medical practitioner to conduct a detailed inspection of the infusion site **382** and associated tubing **400** covered by the flap attaching side **396**. Therefore, the foot guard **390** provides a tamper resistant device that covers a foot infusion site **382** and associated tubing **400** while allowing rapid visual inspection of the foot infusion site **382** for indications of extravasation of medications and degeneration and atrophy of dermal tissues and tissue necrosis proximal of the infusion site **382**.

[0041] Those skilled in the art will recognize that the tamper

resistant guard provides a resilient base panel that offers a multitude of improved features including a resilient flap having a flexible window therein, with the flap hingedly attached to the base panel in overlapping relationship over the panel open portion that is positioned to cover any one or two adjacent sites of a plurality of infusion sites. The panel and protective cover flap window provides rapid visual inspection of the infusion site for identifying extravasation of medications and degeneration and atrophy of dermal tissues, and tissue necrosis proximal of the infusion site. Further, the tamper resistant guard is readily positioned by the medical practitioner on a plurality of anatomic locations on the patient's body or extremities as illustrated herein. The tamper resistant guard is readily repositioned by the medical practitioner by manipulating and reattaching the appropriate panel means for attaching and means for retaining, thereby providing a secure covering over a new infusion site selected by the medical practitioner when the prior infusion site becomes inadequate. Patient tampering with the infusion site and/or the associated tubing is precluded due to the opposing motions required of the patient to one-handledly remove the flap means for fastening from the panel, and to remove the panel from covering the infusion site by disengaging the outer receiving surface from the panel dermal receiving surface.

[0042] Repositioning of the guard device, and adjustment of the intravascular infusion site by a medical practitioner, is rapidly accomplished by disconnecting the panel second means for attaching from the panel means for retaining, and/or manipulation of the window flap attaching side to disconnect from the panel first means for attaching. A medical practitioner can disconnect the infusion tubing, remove the catheter from a first infusion site, and reposition the guard device to cover and protect an adjacent, second infusion site selected by the medical practitioner on the forearm, elbow, upper arm, or on the foot/ankle area. Selection of second or third infusion sites are required when the prior infusion site is in need of rest while the patient receives infusion of medication at another infusion site while tissue degeneration, atrophy and necrosis is treated at the prior infusion site due to extravasation of medicinal fluids. The tamper resistant guard is configured to provide versatility in the positioning of tubing proximal of the infusion site by a plurality of tubing ties protected by covering by the window flap. Those skilled in the art will recognize that the plurality of embodiments illustrated and described herein may not include all uses for the tamper resistant guard, which can be further utilized in alternative configurations on the patient without departing from the spirit and scope of the present invention.

[0043] The present invention is illustrated by description of several embodiments and while the illustrative embodiments have been described in considerable detail, it is not the intention of the applicant to restrict or in any way limit the scope of the appended claims to such detail. Additional advantages and modifications will readily appear to those skilled in the art. The invention in its broader aspects is therefore not limited to the specific details, representative apparatus and method, and illustrative examples shown and described. Accordingly, departures may be made from such details without departing from the spirit or scope of applicant's inventive concept.